IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 11 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF CHARLES HANES, M.D.

Defendants Ethicon, Inc., Ethicon, LLC and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude the general opinions of defense expert Charles Hanes, M.D. *See* Doc. 8561.

INTRODUCTION

Dr. Hanes is a urogynecologist who has practiced medicine since 1971. Ex. B to Doc. 8561, Prolift +M Rpt. at 2. He has been board-certified in Female Medicine and Pelvic Reconstructive Surgery since the certification became available in 2013. *Id.* at 3. In addition to practicing pelvic surgery, he teaches and trains students at the University of South Alabama and has served as a preceptor, teaching hundreds of students how to implant Ethicon's devices. *Id.* at 3, 19-20.

He has performed thousands of surgical procedures for the treatment of pelvic organ prolapse and stress urinary incontinence, using traditional surgical approaches as well as synthetic mesh implants. *Id.* at 3-4; Ex. C to Doc. 8561, TVT Rpt. at 3.

In these cases, Dr. Hanes intends to offer opinions generally addressing the utility and safety of Ethicon's pelvic mesh devices. His opinions are based upon his education, medical

training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other material reflected in his reliance list. Ex. B-C to Doc. 8561, Expert Rpts. His is qualified to opine on these topics and, as detailed below, his opinions are supported by reliable methodology.

Plaintiffs have challenged certain aspects of Dr. Hanes's opinions, and as set forth below, Plaintiffs' arguments lack merit and should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Hanes is qualified to render opinions regarding the utility and safety of Ethicon's devices, and his opinions are supported by reliable methodology.

Plaintiffs claim that Dr. Hanes is not competent to "[g]ive design opinions" on the basis that he has inadequate expertise with the design process and product development, that he supposedly has ignored internal company documents and medical literature, and because he does not know what his personal complication rate is. Doc. 8564 at 4-8. As set forth below, Dr. Hanes does not intend to provide design process opinions, and he is well qualified to testify about the safety and utility of the devices.

A. Dr. Hanes will not provide design process opinions.

Plaintiffs have unsuccessfully made this same challenge to other defense experts in this MDL. Noting that Plaintiffs' challenges are "plagued with confusion about what constitutes a design opinion," the Court has correctly found that similar pelvic surgeon defense experts have "not expressed any opinions about the process of designing a product." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016). Therefore, the Court has denied such challenges to design opinions "as moot." *Id.*

The Court should make the same finding here. Dr. Hanes does not intend to opine about product design and development, and Plaintiffs' motion should not be construed as challenging Dr. Hanes' opinions about the safety and efficacy of the devices.

B. Ethicon's internal product design process documents are irrelevant to Dr. Hanes's safety and utility opinions.

Relying exclusively on this Court's opinion in *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2015), Plaintiffs argue that because Dr. Hanes has not reviewed Ethicon's internal documents about its design process, he cannot opine about any issues that touch upon product design. But. Hanes does not intend to offer *any* opinion regarding the adequacy of Ethicon's internal design procedures or Ethicon's compliance with industry standards during the development of the devices. To the extent that Plaintiffs seek to use Dr. Hanes's failure to review certain design process documents as a basis to exclude his opinions about the safety and efficacy of the devices, Plaintiffs' motion lacks merit and should be denied.

This Court's decision in *Winebarger* lends no support to Plaintiffs' argument. In that case, Boston Scientific challenged the opinion of the plaintiff's proposed expert, Dr. Bobby Shull, regarding Boston Scientific's failure to "follow its own internal protocols" and its "lack of due diligence in the design and development" of the product in issue. *Winebarger*, at *14. Dr. Shull, however, did not review any documents related to Boston Scientific's standard operating procedures or its design protocols. *Id.* Consequently, this Court held that "[w]ithout any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures for the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

In contrast to Dr. Shull in *Winebarger*, Dr. Hanes does not intend to offer any opinions regarding Ethicon's "internal design procedures," and therefore, it was unnecessary for Dr.

Hanes to review any of Ethicon's internal documents related to design procedures. In fact, in *Winebarger*, the Court allowed Dr. Patrick Culligan, a defense expert urogynecologist, to opine about the safety and efficacy of the medical device, even though the Court concluded that Dr. Culligan was not competent to testify about mesh design. *Id.* at *33-35. This Court has found that other physicians with surgical experience were competent to offer opinions similar to that of Dr. Hanes. *See, e.g., Tyree*, 54 F. Supp. 3d at 550; *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9; *Trevino*, 2016 WL 1718836, at *33.

Plaintiffs have chosen to focus on an opinion Dr. Hanes has not offered related to documents Dr. Hanes was not even asked to review. Quite simply, Plaintiffs have not shown and cannot show that a review of Ethicon's internal product design process documents was necessary for any of the opinions that Dr. Hanes intends to provide in these cases.

C. Dr. Hanes's opinions are reliably based on medical literature.

Plaintiffs nit-pick Dr. Hanes's opinions because he is not aware of certain literature supporting Plaintiffs' theories in this MDL. Doc. 8564 at 6. Dr. Hanes's reports, however, set forth citations to numerous scientific articles, demonstrating that he has a thorough grasp of the pertinent medical literature. *See, e.g.*, Ex. B to Doc. 8561, Prolift +M Rpt. 4-17, 22-23, Ex. C to Doc. 8561, TVT Rpt. at 17- 26, 33-34. As noted by Dr. Hanes: "I've reviewed tons of literature that have referred to the products, as well as potential problems and complications, just in the course of my career, yes." Ex. D. to Doc. 8561, Hanes Dep. 58:3-6. He also acknowledges studies frequently cited by Plaintiffs. *See, e.g.*, Ex. C. to Doc. 8561, TVT Rpt. at 33 (referencing Clave article).

The Court rejected a similar argument in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521 (S.D. W. Va. May 19, 2016). The plaintiff in that case challenged defense expert

Stephen Badylak, M.D.'s competence to testify about the safety and efficacy of polypropylene mesh devices on the basis that Dr. Badylak had admitted that he had not performed a "comprehensive review" of the scientific literature related to the defendant's devices." *Id.* at *41. The Court, however, noted that Dr. Badylak's report demonstrated that he "reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices," and that "[i]f there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Id.*; *see also id.* at *5 (S.D. W. Va. Apr. 28, 2016) (finding that "to the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility" and that "[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions").

Applying the Court's reasoning to these cases, Dr. Hanes plainly has performed a sufficiently thorough review of the medical literature to ensure the reliability of his opinions. Plaintiffs' challenges are appropriate for cross-examination.

D. Dr. Hanes's personal complication rate is irrelevant.

Curiously, Plaintiffs claim that Dr. Hanes's opinions are unreliable because he cannot testify with any specificity his personal complication rates. Doc. 8564 at 7. This may serve as a basis to exclude Dr. Hanes from speculating at trial about his personal complication rates, but it certainly does not serve as a basis to exclude other opinions, such as that the devices are safe and effective. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D.W. Va. Nov. 20, 2014) ("If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial

motions"); *Winebarger v. Boston Scientific Corp.*, 2015 U.S. Dist. LEXIS 53892, at *99 (S.D. W. Va. Apr. 24, 2015) (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device"); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *33 (S.D.W. Va. Apr. 28, 2016) (same).

This Court has also recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp,* 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (expert applied reliable methodology supporting opinion that product was safe and effective where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, 36 (S.D.W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare). That is precisely what Dr. Hanes will do in these cases. Any alleged inconsistencies or weaknesses in Dr. Hanes's testimony go to its weight, not its admissibility. *See Daubert,* 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence").

Indeed, Dr. Hanes's extensive personal experiences, coupled with his reliance on the medical literature, make him well qualified to opine about the safety and utility of the devices.

He is a skilled urogynecologist with decades of experience treating female pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. He has performed thousands of surgical procedures for the treatment of pelvic organ prolapse and stress urinary incontinence, using traditional surgical approaches as well as synthetic mesh implants; and he has served as a professor and preceptor of Ethicon's devices, teaching hundreds of students how to implant the devices. Ex. B to Doc. 8561, Prolift +M Rpt. at 3-4, 19-20; Ex. C to Doc. 8561, TVT Rpt. at 3. He is well qualified to offer his opinions, and there is no basis to Plaintiffs' challenge.

II. Dr. Hanes is qualified to testify regarding the adequacy of warnings.

Dr. Hanes has opined on the completeness and accuracy of the devices' warnings from a clinical perspective based on his knowledge of and clinical experience with the devices. Ex. B to Doc. 8561, Prolift +M Rpt. at 23, Ex. C to Doc. 8561, TVT Rpt. at 30. Plaintiffs do not challenge, or even address, Dr. Hanes's clinical expertise. Instead Plaintiffs argue that he is not qualified to opine on the adequacy of the IFUs because he is not a warnings expert.

Ethicon concedes that Dr. Hanes is not a regulatory expert and will not opine on warnings from that perspective. As noted by Dr. Hanes, however, he considers himself to be a warnings expert from a clinical perspective, including based on his extensive experience "training doctors." Ex. D to Doc. 8561, Hanes Dep. 85:20-86:20.

Dr. Hanes is just as qualified (if not more qualified) to offer warnings opinions as other pelvic surgeon experts in this MDL. Consistent with the Court's prior rulings related to similarly-qualified pelvic surgeons, the Court should find that Dr. Hanes "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon*, 2016 WL 4582231, at *3. Dr. Hanes's reports detail his extensive experience with

these devices, including particular risks and complications he has experienced and researched. His extensive clinical experience with the products in issue is supplemented by a very thorough review of the relevant literature and education he has provided to others.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude Dr. Hanes's testimony.

Respectfully submitted,

/s/ *William M. Gage*
William M. Gage (MS Bar No. 8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ *Susan M. Robinson*
Susan M. Robinson (W. Va. Bar No. 5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

Counsel for Defendants

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
William M. Gage